

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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TRUSTEES OF BOSTON UNIVERSITY,)

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Plaintiff,)
)

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v.)

03-CV-10095-MEL

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BEACON LABORATORIES, INC.,)
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Defendant.)
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MEMORANDUM AND ORDER

LASKER, D.J.

In December 2002, a panel of arbitrators awarded Beacon Laboratories, Inc. (Beacon) \$2,834,442 in an arbitration that it brought against the Trustees of Boston University (BU). BU sues to vacate the arbitration award on the grounds that it was issued in manifest disregard of the law.

Beacon moves for summary judgment affirming the award. The motion is GRANTED.

I.

In 1993, BU filed an application with the Patent and

Trademark Office (PTO) seeking protection for uses of an organic compound, arginine butyrate, to treat cancer and gastrointestinal disorders, and to heal wounds. In 1995, BU licensed rights to this application to Emerging Pharmaceutical Technologies (EPT), which subsequently assigned those rights to Beacon. The license agreement granted exclusive rights to develop arginine butyrate for treating cancer, gastrointestinal (GI) disorders, and wounds, but did not guarantee that any patents would issue. In return, BU received reimbursement of its patent expenses, a license fee of \$17,500 (which amounted to a reimbursement of most, but not all, pre-license patent costs) and, for three years beginning in 1997, an annual minimum royalty of \$10,000. The agreement also provided for additional royalties to be paid to BU if profits were generated by Beacon.

At the time the agreement was executed, the cancer component of the application had already been rejected twice by the PTO. It has still not issued. The wound treatment aspect of the patent issued in 1999.¹

Dr. Douglas Fuller was the only inventor named in the application. As a member of the faculty of the BU School of Medicine, Fuller assigned his rights to BU in accordance with

¹ The parties have not specified whether the GI aspect of the patent has issued; this fact, however, is immaterial to the disposition of the present motion.

university policy. In the licensing agreement, BU represented that "it is the owner of the entire worldwide right, title and interest in and to the Licensed Patent Rights and Technology as defined . . . and that it has the right to grant licenses under said licensed Patent Rights and Technology." In 1996, however, BU reviewed its patent portfolio and concluded that Faller was not the sole inventor of the work described in the application. This was so because the research leading to the application was conducted jointly by Faller and Dr. Susan Perrine, who, at the time the research was conducted, was employed at Children's Hospital of Oakland, California. BU was unable to obtain assignments giving it the exclusive rights. The result of BU's error is that Beacon secured partial, rather than exclusive, rights to develop the cancer and gastrointestinal aspects of the application, and no rights to develop the wound-healing aspect.

Beacon, claiming that it expended money in reliance on the rights it had been promised in the agreement, filed a demand for arbitration in September 2000. Following thirteen days of hearings, the panel rendered an award for Beacon. The award was issued by the neutral arbitrator and Beacon's party-appointed arbitrator. BU's party-appointed arbitrator wrote a dissenting opinion.

Both the majority and the dissent concluded that BU had

breached the agreement and that Beacon had expended the money in seeking to develop a cancer drug. Both concluded that Beacon would not have recouped these expenses even if it had possessed exclusive rights to either the cancer or GI aspects of the patent application; in the words of the majority opinion, "[h]indsight reveals that the arginine butyrate patent applications and Technology covered by the License Agreement are not efficacious when applied to cancer and show little promise in GI applications." (Ex. 1 to Pl.'s Mem., at 4-5.)

At this point, however, the majority and dissent diverge. The majority concluded that Beacon should be awarded damages reflecting the amount that, in the majority's view, Beacon could have recouped through development of a wound-healing drug. More precisely, the majority concluded that BU had failed to meet its burden of establishing that Beacon would not have recouped its expenses with profits from developing the wound-healing applications of the substance:

When considering reliance damages, Massachusetts courts allocate the burden of proof. The plaintiff bears the initial burden of proving the sum, if any, it spent in reliance on the defendant's unfulfilled contractual promise. If plaintiff meets that threshold, the defendant then bears the burden of showing plaintiff would have received no economic benefit from defendant's contractual performance, or a benefit less than the amount spent by plaintiff

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The Licensed Patent Rights and Technology appear valuable for treating wounds. . . . Had Beacon held the exclusive rights to an issued patent on the use of arginine butyrate to treat wounds, it would have had . . . 20 years, the life of the patent, to exploit commercially the wound healing patent rights, including through outlicensing or other program [sic]. . . . BU has failed to prove that Beacon would not have had such a program; the weight of the credible evidence shows otherwise.

(Id. at 2, 4-5.)

The dissent, in contrast, concluded that Beacon had shown no interest in the wound-healing aspect of the substance, would never have made any money even if it had possessed the rights to this aspect of the application, and thus was not entitled to the award because, contrary to Massachusetts law, such an award placed Beacon in a better position than if there had been no breach.

II.

Beacon argues that the arbitrators' award should be affirmed because no material facts are in dispute, and because the award is final and binding. It contends that although the Federal Arbitration Act (FAA) provides for judicial review of an arbitration award, see 9 U.S.C. § 10, such review is "among the

narrowest known in the law." First State Ins. Co. v. Bancos de Seguros del Estado, 254 F.3d 354, 357 (1st Cir. 2001) (citation omitted). As to the "manifest disregard of the law" standard that BU invokes here, Beacon notes that the First Circuit has limited such findings to "instances where it is clear from the record that the arbitrator recognized the applicable law - and then ignored it." Advest, Inc. v. McCarthy, 914 F.2d 6, 9 (1st Cir. 1990). Beacon argues that BU has offered no evidence that the majority arbitrators did any such thing, and notes that mere misapplication or error of law does not warrant vacatur of an award. Wonderland Greyhound Park, Inc. v. Autotote Systems, Inc., 274 F.3d 34, 35 (1st Cir. 2001).

BU responds that although arbitrators' findings of fact generally may not be challenged, the principle does not apply where an award is insufficiently grounded in the record. Gupta v. Cisco Systems, Inc., 274 F.3 1,3 (1st Cir. 2001). According to BU, while the arbitration focused on Beacon's rights to develop arginine butyrate to create a cancer drug, and the damages aspects of the hearings focused almost entirely on whether Beacon would have secured a profit if it had possessed the exclusive rights to the cancer component of the application, the panel rendered a decision about the potential benefits Beacon might have secured if it had received the wound-healing patent.

Rather than giving Beacon the benefit of the bargain, BU contends, the arbitrators gave it a windfall.

The result, BU argues, is in "manifest disregard" of Massachusetts contract law, which requires that a party alleging breach of contract prove both causation and foreseeability in order to recover damages. See John Hetherington & Sons, Ltd. v. William Firth Co., 210 Mass. 8, 21-22, 95 N.E. 961, 964 (1911); see also Augat, Inc. v. Aegis, Inc., 417 Mass. 484, 488, 631 N.E.2d 995, 998 (1994) (damages for lost profits are recoverable only when proof is made with sufficient certainty). The majority disregarded these requirements, BU contends, in awarding damages when Beacon had not introduced any evidence that it anticipated any profit from the wounds patent. According to BU, the un rebutted evidence shows that Beacon spent no money developing the wound-healing patent, and the "lost" patent rights had little, if any, value to Beacon or anyone else. BU further contends that the majority incorrectly relied on financial projections articulated by Perrine and Faller in the business plans of their private company, Gene Regulation Laboratories (GRL). BU notes that to date, GRL has been unable to raise money or secure a sublicensing deal, and that there is no evidence that Beacon would have been any more successful. Moreover, BU notes, GRL's own documents indicate that wound healing is an

entrepreneurial minefield in which it is extremely difficult to turn a profit.

BU urges that the following propositions must be considered in evaluating the arbitration award: (1) Beacon's sole focus since its founding has been on cancer drugs.² (2) Because the patent at issue here is a "use" patent, it would not have provided Beacon with a significant barrier to prevent others from competing in the field.³ (3) A patent holder cannot enter the marketplace without FDA approval, which Beacon had not obtained. (4) Beacon failed to develop arginine butyrate; BU points out that by 1998, having failed to raise additional money and having concluded that arginine butyrate was both too difficult to administer⁴ and ineffective, Beacon had moved away from the field. (5) Beacon would not have recovered its investment in developing arginine butyrate because it had concluded that it had more efficacious drugs, with better patent protection, in its portfolio.

² BU cites testimony stating that Beacon secured financing only upon the condition that it attempt to develop a cancer drug.

³ A use patent does not prevent competitors with a patent for a different use of the same drug from undercutting the market: for example, a physician can prescribe a competitor's version of the same drug for the patent holder's use.

⁴ The compound cannot be taken orally, and requires cumbersome intravenous administration.

III.

The licensing agreement provides that "[t]he award of a majority of the arbitration panel shall be final and binding on the parties thereto and shall be enforceable in any court having jurisdiction." "[N]on-reviewability [of arbitration awards] remains the general rule - and exceptions are few and far between." Advest, 914 F.2d at 8. The First Circuit has instructed that "[a]n arbitrator's award must be enforced if it is in any way plausible, even if we think [the arbitrator] committed serious error." Wonderland Greyhound Park, 274 F.3d at 35 (internal quotations and citations omitted). In Advest, the court stated that to establish "manifest disregard" for the law:

there must be some showing in the record, other than the result obtained, that the arbitrators knew the law and expressly disregarded it. In this context, 'disregard' implies that the arbitrators appreciated the existence of a governing legal rule but willfully decided not to apply it.

Advest, 914 F.2d at 10 (internal quotations and citations omitted, emphasis added).

BU has failed to make the showing required by the First Circuit in Advest and Wonderland Greyhound Park. Although the dissenting opinion points out serious weaknesses in the majority's conclusions, these weaknesses do not constitute a willful refusal to apply the law. The majority considered the

arguments that BU presents here, and found that they were not persuasive. As they said: "BU failed to prove that Beacon would not have had [a wound healing] program; the weight of the credible evidence shows otherwise." (Ex. 1 to Pl.'s Mem., at 4-5.) Beacon notes that although its original focus was on developing a cancer drug, much of its work to develop arginine butyrate concerned issues such as human safety that would have been equally applicable to developing the substance to treat wounds.

Under the extremely narrow standard of review that governs arbitration awards, there is no ground for vacatur. Accordingly, the motion for summary judgment is GRANTED. The case is dismissed.

It is so ordered.

Dated: May 6, 2003
Boston, Massachusetts



U.S.D.J.